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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,254	06/17/2002	Elisabeth E. Adderson	1321.2.29.1	8298

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/009,254	Applicant(s) ADDERSON ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-67 ~~is~~ are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**Lack of Unity of Invention(s)**

1) Claims 1-67 are under prosecution.

2) The instant inventions lack unity under PCT Rule 13.1 and 13.2:

- I. Claims 1-16, drawn to an isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 2, a vector and a host cell comprising the same, and a diagnostic PCR method.
- II. Claims 17-32, drawn to an isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 4, a vector and a host cell comprising the same, and a diagnostic PCR method.
- III. Claims 56-60 and 33-37, drawn to an isolated protein comprising the amino acid sequence of SEQ ID NO. 2, and a method of immunizing a mammal by administering a protein comprising the protein.
- IV. Claims 61-67 and 38-40, drawn to an isolated protein comprising the amino acid sequence of SEQ ID NO. 4, and a method of immunizing a mammal by administering a protein.
- V. Claims 42, 50 and 54, drawn to a diagnostic method for determining group B streptococcal infection or colonization by detecting the *spb1* gene product.
- VI. Claims 43, 51 and 55, drawn to a diagnostic method for determining group B streptococcal infection or colonization by detecting the *spb2* gene product.

Claims 41, 44-49, 52 and 53 are linking claims and would be joined with one of inventions V and VI, if elected.

3) Inventions I-VI lack unity of inventions. These inventions do not relate to a single inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features. The special technical feature of the first claimed product of invention I is an isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 2, a vector and a host cell comprising the same. The special technical feature of the second claimed product of invention II is an isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 4, a vector and a host cell comprising the same. The special technical features of inventions III and IV respectively, are an isolated protein comprising the amino acid sequence of SEQ ID NO. 2 and 4,

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and a method of using the respective protein. The four products do not share significant structural features. The methods of inventions VII and VIII and of inventions III and IV do not share significant method steps and reagents or compositions used in the methods.

4) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A telephone message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

October, 2004

  
S. DEVI, PH.D.  
PRIMARY EXAMINER